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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,032	06/29/2001	Christoph Seidel	HUBR-1067.3 DIV	2111

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
WORTMAN, DONNA C	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,032	SEIDEL ET AL.	
	Examin r	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/511,759* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 27-36 were canceled, claim 38 was amended and claims 39-49 were added in Paper No. 11. Claims 37-49 are pending and under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39 and 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 49 recite "A method for recognition of hepatitis C ... seroconversion" but recite only two steps, an "incubating" step, and a "determining" step. It is not understood how "seroconversion" can be recognized in a sample taken from a subject at a single time point; clearly some comparison would be required. Lacking enough steps to define a method for recognition of seroconversion, claims 39 and 49 are incomplete and merely define an immunoassay as presently recited.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39 and 49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP06074956, with English translation, of record. JP06074956 discloses that immunoassays using antigens from the HCV NS3 region are improved by being conducted in the presence of a reducing agent in order to prevent aggregation due to the relatively cysteine-rich nature of the NS3 region. Because claims 39 and 49 are incomplete as discussed above, and recites only minimal immunoassay steps, JP06074956 is deemed to anticipate the method as claimed because a process is defined by process steps. Alternatively, the immunoassays of JP06074956 differ, if at all, from the subject matter of claims 39 and 49 only by not explicitly teaching a "seroconversion" assay; however, since JP06074956 teaches generally that using a reducing agent in an immunoassay that employs an HCV NS3 antigen to detect HCV antibodies improves sensitivity, it would have been obvious to use a reducing agent in a seroconversion assay in order to gain the advantage of improved sensitivity.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP06074956 in view of either of Beach et al. (Journal of Medical Virology 36(3):226-227, 1992) or Vallari et al. (Journal of Clinical Microbiology 30(3):552-556, 1992), of record, for reasons of record in rejecting claims 37 and 38 in the previous Office action.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP06074956 in view of Vallari et al. and of US Patent Re. 32,696 to Schuurs et al., of record, essentially for reasons of record. Vallari teaches detection of seroconversion in human patients.

Insofar as Applicant's arguments are deemed to apply to the rejections as now offered, they will be addressed here.

Applicant has argued (1) that Beach applies only to seroconversion in chimpanzees; (2) that Vallari did not carry out two tests for antibodies to NS3; (3) that JP06074956 used a mixture of c33 and c100 antigens and could not determine to which antigen the antibodies bound; and that the art does not suggest determining NS3 specific antibodies to determine seroconversion.

These arguments have been considered but not found persuasive. First, it is noted that the inclusion of claim 27 in the rejection over JP06074956 and either of Beach et al. or Vallari et al. in the previous Office action was a typographical error that should have read "claim 37"; this should be readily apparent since the term "seroconversion" discussed in the rejection appears in claim 37 but did not occur in claim 27. Addressing Applicant's arguments in the order summarized above, it is noted that (1) Beach is not now applied to claims limited to human subjects.

(2) Vallari shows the detection of antibodies using NS3 antigen over a course of time after transfusion, and clearly illustrates seroconversion antibodies detected by NS3 antigen in human patients. See, e.g., Figs. 2-4, solid line connecting square symbols.

(3) JP06074956 clearly teaches the use of HCV NS3 antigen in presence of a reducing agent; see e.g., end of [0008] of the English translation: "As the HCV antigen being used in the present invention, a HCV antigen corresponding to NS3 area of an unstructured area on the HCV genom is preferably mentioned."

Claims 40-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A terminal disclaimer over US Patent No. 6,270,960 is of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw